

Remarks

Claims 1, 2, 4, 8, 9, 14 and 17 have been amended. Claims 2, 4, 9 and 17 have been amended in order to clarify the claim language.

Claims 5 and 6 have been cancelled.

Claims 20 and 21 have been added.

Minor typographical errors in the specification have been corrected.

Applicants thank the Examiner for returning the initialed PTO Form 1449 submitted on February 27, 2001. A different Information Disclosure Statement, and accompanying PTO Form 1449 and copies of cited documents, had been transmitted to the Patent Office on June 22, 2001. Applicants request initialed copies of that form PTO-1449 to indicate that the references provided therein have been considered.

35 U.S.C. §102

MPEP 2131 quotes Verdegaal Brothers v. Union Oil of California, 814 F.2d 628, 631 (Fed. Cir. 1987) for the legal standard of anticipation: "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." (emphasis added).

Claims 1-4, 7, 20-21

Claim 1 has been amended to claim, among other elements, an anastomosis device having "a device body formed of a superelastic or pseudoelastic material, the body having an insertion configuration and a tissue holding configuration in which the body has an inner flange and an outer flange, the outer flange having a plurality of outer flange members and the

inner flange having a plurality of inner flange members, wherein at least one of the outer flange members is radially offset from at least one of the inner flange members in the tissue holding configuration.” The phrase “radially offset” means occupying a different position along the circumference of the anastomosis device than another member. That is, looking along the longitudinal axis of the anastomosis device, two members are radially offset from one another if they occupy different positions along the circumference of the anastomosis device. Lines extending between two different circumferential positions and the longitudinal axis necessarily form an angle. Support for this amendment is found, among other locations, at Figure 1. More inner flange members are present than outer flange members, such that at least one of the inner flange members necessarily is radially offset from at least one of the outer flange members.

In contrast, Peterson neither teaches nor suggests an outer flange having a plurality of outer flange members and an inner flange having a plurality of inner flange members, wherein at least one of the outer flange members is radially offset from at least one of the inner flange members in the tissue holding configuration. Rather, Peterson discloses flange members that are radially aligned with one another, such that tissue is held between pairs of corresponding inner flange members and outer flange members. (e.g., Peterson, column 5, lines 20-23 (“plurality of internal opposition fingers 18 are positioned adjacent a plurality of external opposition fingers 20”); column 6, lines 52-55 (“adjacent ones of fingers 18 and 20...define a ‘U’-shaped configuration”); Figures 1, 14, 29). Thus, rather than being radially offset from one another, the inner flange members and outer flange members of Peterson are necessarily radially aligned with one another, such that tissue is compressed between corresponding pairs of inner flange members and outer flange members. Indeed, Peterson claims a connector having two pluralities of fingers, corresponding to the inner flange members and the outer flange members, “wherein the pluralities of fingers are substantially radially aligned with

respect to a longitudinal axis.” (Peterson, claims 2, 11, 12, 17, 19). Nowhere does Peterson disclose an inner flange member radially offset from an outer flange member. Thus, Peterson neither teaches nor suggests each and every element claimed in amended claim 1.

Turning to Berg, that reference discloses an artificial graft vessel integral with hooks for connecting that artificial graft to a target vessel. Thus, Berg necessarily does not and cannot disclose a “one-piece anastomosis device for connecting a graft vessel to a target vessel.” In addition, Berg neither teaches nor suggests an outer flange having a plurality of outer flange members and an inner flange having a plurality of inner flange members, wherein at least one of the outer flange members is radially offset from at least one of the inner flange members in the tissue holding configuration. Instead, Berg discloses an artificial graft having inner flange members and outer flange members defined in at least one end thereof, where those members are radially aligned with one another. (*e.g.*, Berg, Figures 3, 10c, 12, 21). Thus, Berg neither teaches nor suggests each and every element claimed in amended claim 1.

Neither Peterson nor Berg teaches nor suggests each and every element claimed in amended claim 1, and Applicants consequently believe claim 1 is in condition for allowance. Claims 2-4, 7, and 20-21 depend directly or indirectly from claim 1, and are thus believed to be in condition for allowance as well. Claim 4 also has been amended to clarify the language of the claim.

Claims 8-13

Claim 8 has been amended to claim, among other elements, an anastomosis device formed of a superelastic or pseudoelastic material, the device having an insertion configuration and a tissue holding configuration in which the device has an inner flange and an outer flange, the outer flange having a plurality of outer flange members and the inner

flange having a plurality of inner flange members, wherein at least one of the outer flange members is radially offset from at least one of the inner flange members in the tissue holding configuration.

The discussion above with respect to amended claim 1 applies equally here. Neither Peterson nor Berg teaches nor suggests each and every element claimed in amended claim 8, and Applicants consequently believe claim 8 is in condition for allowance. Claims 9-13 depend directly or indirectly from claim 8, and are thus believed to be in condition for allowance as well. Claim 9 also has been amended to clarify the language of the claim.

Claims 14-19

Claim 14 has been amended to claim, among other elements, deploying the one piece device by self deformation to a tissue holding configuration in which the device has an inner flange and an outer flange and traps the target vessel tissue between the inner flange and the outer flange, the outer flange having a plurality of outer flange members and the inner flange having a plurality of inner flange members, wherein at least one of the outer flange members is radially offset from at least one of the inner flange members.

The discussion above with respect to amended claim 1 applies equally here. Neither Peterson nor Berg teaches nor suggests each and every element claimed in amended claim 14, and Applicants consequently believe claim 14 is in condition for allowance. Claims 15-19 depend directly or indirectly from claim 14, and are thus believed to be in condition for allowance as well. Claim 17 also has been amended to clarify the language of the claim.

REQUEST FOR ALLOWANCE

Allowance of the pending claims is respectfully solicited. Please contact the undersigned if there are any questions.

Respectfully submitted,



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